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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,593	03/30/2004	Bernard Andreas	021629-002500US	5895

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EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	**PAPER NUMBER**
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,593	ANDREAS ET AL.	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/10/10 has been entered.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant's arguments with respect to finding proper support in application 10/637,713 is persuasive. As such the effective filing date for the instant application will be 08/08/2003, the filing date of application 10/814593.

Claim Objections

2. Claims 53 and 64 are objected to because of the following informalities: Claims 53 and 64 state that the stents are "unattached with each other" but later states that the "stents are in direct contact with one another when unexpanded". Since "attached" is generally interpreted as *joined*, examiner requests better clarification to distinguish

"unattached" (unjoined) with respect to "in direct contact" (joined). Examiner suggests language such as --- *not fixedly attached* --- or --- *not rigidly attached* ---.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 53, 54, 56-62, 64, 65, 67, 69-71 and 73-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US 2002/0793873) in view of Anderson (WO 03/022178) and further in view of Brucker (US 2002/0793873).

5. With respect to claims 55 and 64, Chermoni discloses a method of treating one or more lesions in a vessel, the method comprising: providing a plurality of stents comprising a first, second and third stent (206a, 206b, 206c) positioning a delivery catheter (Fig. 11) in the main branch, the delivery catheter having an expandable member (704) disposed thereon, wherein one stent is positioned over the expandable member (Fig. 12); radially expanding the expandable member thereby radially expanding the first stent in the main branch; positioning the delivery catheter at a different location; and radially expanding the expandable member thereby radially expanding the second stent; wherein the delivery catheter remains in the vessel between radially expanding the first and second stents (Para [009]); Claims 57 and 70: the first stent has a different overall length than the second stent (Para [0005]; [0047]);

Claims 58 and 59: the first stent can be deployed before the second stent or the second stent can be deployed before the first stent (Para [0049]); Claim 61 and 62: adjusting the length of the first and second stent before deploying the first and second stent while the delivery catheter remains in the vessel (Para [0008] states that the stents may be delivered in any order and may be different lengths and so the lengths are adjusted by choosing a different order of stents).

6. Chermoni does not disclose that the first stent comprises first and second stent segments wherein the step of radially expanding comprises expanding the first and second stent segments concurrently. However, Anderson teaches a single stent device having a multiple stent segments whereby the stent segments are unattached when unexpanded and in direct contact when unexpanded (Page2:L22-28). The detached stent segments achieve the advantage of greater longitudinal flexibility, better conformability, reduced foreshortening and ease of manufacture (Page 13:L26-Page14:L14) It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate stents with detachable segments into the method and device of Chermoni in order to achieve the same advantage taught by Anderson. In light of the modification, it would follow that the first and second stent segment making up the first stent would be expanded concurrently. In light of the modification, with respect to claims 56 and 71: the first and second stents each comprise a plurality of separable segments and the second stent would comprise a third segment. Claim 54: It follows that the plurality of stents comprises a fourth segment. Claims 73 and 76: selecting a first number of separable segments comprising the first and second stent

segment having a first length for radial expansion and selecting a second number of separable segments comprising the third stent segment for radial expansion wherein the first number of segments is different from the second number of segments (where Chermoni teaches delivering stents of different lengths (Para [0005]; [0047]), thus it follows in light of the modification that the different lengths would include different numbers of segments). Claims 74, 75, 77 and 78: the step of selecting comprises moving a sheath or a pusher tube (where 114 of Chermoni can be a sheath or a pusher tube and stents can be delivered in any order (Para [0008]).

7. Modified Chermoni does not disclose a method that incorporates delivering a second stent to a side branch or that the delivery catheter is positioned through an opening in a sidewall of the first stent to deploy the second stent. However, Brucker discloses a method of treating one or more lesions in a vessel, the vessel having a main branch and a side branch branching from the main branch at a bifurcation, the method comprising similar steps to those that are disclosed by modified Chermoni such as positioning the delivery catheter at multiple lesions and expanding first and second stents at different locations without removing the catheter from the body. Brucker further discloses with respect to claims 53 and 64 positioning a delivery catheter (112) in the main branch, and radially expanding the expandable member thereby radially expanding a first stent (94 or 114) in the main branch across the bifurcation (Fig. 13, 14, 17 and 18; Para [0083]); positioning the delivery catheter in the side branch and radially expanding an expandable member (120) thereby radially expanding a second stent (74 or 116) in the side branch (Fig. 10-12, 20, Para [0084]); wherein the delivery catheter is

not removed from the vessel between deploying the first and second stent segments and the third stent segment (see Figs. 18-20; Para [0084]); With respect to claim 55: the delivery catheter is positioned through an opening (16) in a sidewall of the first stent to deploy the second stent (Fig. 20); Claim 60: wherein the first stent and the second stent each have a portion in the main branch. (Fig. 14, 16, 17); Claim 65: dilating an opening in the first stent by expanding the expandable member on the delivery catheter (Fig. 20 when the stent is expanded); Claim 67 wherein the first stent has a first portion with a plurality of first slots (for example at scaffold 14) and a second portion with a plurality of second slots (openings formed by mesh pattern in rest of stent), the first slots being larger than the second slots; Claim 69: wherein the first stent has a different geometry than the second stent (the first stent has a side opening).

8. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the method of treating a bifurcated vessel into the method and apparatus of modified Chermoni. Both modified Chermoni and Brucker disclose similar devices for multiple stent delivery. Brucker discloses an additional method of delivering the multiple stents to lesions in a bifurcated vessel having a main vessel and a branch vessel. One of ordinary skill would have been capable of applying this known technique of enhancement (delivering stents to a bifurcated vessel) to a base device (multiple stent delivery catheters) in order to yield predictable results namely providing an efficient way of delivering multiple stents to multiple lesions at a bifurcation. If a technique has been used to improve one device, and a person of ordinary skill in the art

would recognize that it would improve similar devices in the same way, applying the technique to a similar device would have been obvious.

9. Claims 55, 66, 68, 72, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US 2002/0156496) in view of Anderson (WO 03/022178) and Brucker et al. (US 2002/0193873) as applied to claims 53 and 64 above and further in view of Fischell (US 5,697,971).

10. Modified Chermoni discloses a method of treating a lesion in a bifurcation but does not disclose that the first and second stent has plurality of sidewall openings expandable to allow deployment of a stent. However, Fischell discloses a stent structure that incorporates a plurality of sidewall openings for deploying a stent through (12, Fig. 2 and Figs. 4a-4d). Claim 66: the openings are I shaped (Fig. 2). With respect to claims 67 and 68 there are first slots (12) that are larger than second slots (11) wherein the opening for deploying the third stent is a first slot and the slot would be aligned with the bifurcation (Fig. 4a-4d). Claim 79 and 80: the plurality of openings is expandable to a diameter substantially equal to an expanded diameter of at least on of the first, second or third stents. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the cell structure of Fischell into the Richter stent and the modified delivery device of Chermoni such that the first and second stent both comprises the plurality of sidewall openings, as in claim 72, in order to achieve the advantage of easily locating the sidewall opening at the branch for delivering a branch stent (Fischell C1:L10-25).

11. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni in view of Anderson (WO 03/022178) and Brucker et al. (US 2002/0193873) as applied to claims 53 and 64 above and further in view of Shaknovich (US 5,807,398).

12. Modified Chermoni does not explicitly state the step of dilating at least one lesion in the vessel using an expandable member on the delivery catheter before deploying at least one of the first and second stents. However, Chermoni does contemplate the multiple steps of balloon angioplasty and stent delivery when discussing prior art (Para [003]). Shaknovich discloses a single catheter multiple stent delivery device similar to Chermoni modified by Brucker and explicitly discloses using the expandable member to pre-dilate a vessel prior to stent delivery in order to provide an adequate passageway for the delivery catheter (C 12: 20-29). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the step of dilating a lesion prior to stent delivery into the method disclosed by Chermoni modified by Brucker. Pre-dilating the vessel prior to stent delivery is old and well known in the art and provides the advantage of increasing the diameter of the passage to allow the catheter to get through.

Response to Arguments

13. Applicant's arguments with respect to claim 53-78 with respect to prior art have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth Houston/
Examiner, Art Unit 3731